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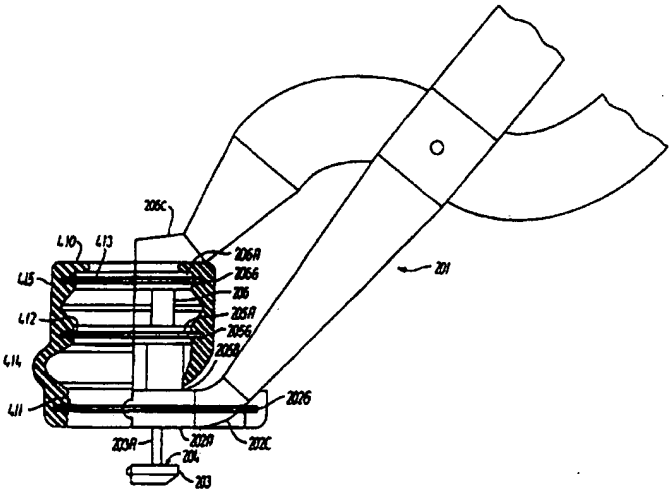

(57) Abstract

An anastomotic instrument (201) and a method for establishing an end-to-side anastomosis. The instrument comprising an anvil assembly (202A, 203, 203A), having stapling recesses (204), a clamping assembly (205B, 205A) adapted to be advanced towards said rear face of said anvil (203), and a stapling assembly (206, 206A), to be moved towards said anvil (203). The main novel features are that all three assemblies can be split along a common dividing surface, and that during the operation, the separable parts of the assemblies are held together by a common elastic rubber sheath (410), to ensure a correct sequence of relative movement when the three assemblies are pressed together by a manual implement having jaws (202C, 206C). After the anastomosis has been established, the rubber sheath (410) may be cut open to enable the separable parts to be separated from each other.

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METHOD AND ANASTOMOTIC INSTRUMENT FOR USE WHEN PERFORMING AN END-TO-SIDE ANASTOMOSIS

TECHNICAL FIELD

The present invention relates to a method of the kind set forth in the preamble of claim 1.

BACKGROUND ART

A method of this kind is described in the international application PCT/DK95/00430. In this previous method, the various relatively movable assemblies, viz. the anvil assembly, the clamping assembly and the stapling assembly, extended circumferentially all the way around the internal space in the instrument accommodating the first vessel or graft vessel, for which reason it was necessary when removing the instrument from the anastomosis having been established to move it along the graft vessel to the latter's free end or to pull the graft vessel out of the instrument.

This means, of course, that the instrument of said application PCT/DK95/00430 can only be used with totally free graft vessels leaving one free end after anastomosis, making it possible to use the instrument for establishing anastomoses at both ends of an originally free graft vessel - or at the only free end of a closely situated anatomical artery (typically, but not exclusively the Internal Mammarian Artery - the socalled IMA vessel), such as may be required in coronary surgery.

DISCLOSURE OF THE INVENTION

It is the object of the present invention to provide a method of the kind referred to above, with which it is possible to use the instrument for establishing anastomoses at any free end of a graft vessel, such as may be required in coronary surgery, and this object is achieved by proceeding as set forth in the characterizing clause of claim 1. In this manner, the instrument may be divided along the internal space accommodating the graft vessel, the two parts arising out of this dividing being removable sideways from the graft vessel, so that the latter does not necessarily have to have a free end.

The present invention also relates to an anastomotic instrument for carrying out the method according to the invention, and this instrument is characterized by the features set forth in claim 5.

Advantageous embodiments of the method and the anastomotic instrument according to the invention, the effects of which - beyond what is self-evident - are explained in the following detailed part of the present description, are set forth in claims 2-4 and 6-8 respectively.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following detailed part of the present description, the invention will be explained in more detail with reference to the exemplary embodiments of an anastomotic instrument according to the invention shown in the drawings, in which

Figures 1-8 show the process of performing an end-to-side anastomosis using an anastomotic instrument

according to the invention subject of the application PCT/DK95/00430 referred to initially, Figures 1-7 being drawn in a highly simplified manner for ease of understanding,

Figures 9-12 in perspective and with certain parts cut away show a practical embodiment of an anastomotic instrument according to the aforesaid invention with the various possible relative positions of the relatively movable parts,

Figure 13 at a highly enlarged scale shows a part of the instrument shown in Figure 1 with modified clamping surfaces, and

Figures 14-18 show the anastomotic instrument according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As mentioned above, the embodiment shown in Figures 1-8 of the anastomosis instrument according to the invention subject of the application PCT/DK95/00430 constitutes a simplified version with the primary purpose of explaining the invention; this does not, however, preclude the possibility of using this embodiment in actual practice.

Thus, Figure 1 shows an anastomosis instrument 1 consisting of three main components that are movable relative to each other in the longitudinal direction, i.e. in the direction shown as the vertical direction in Figure 1:

- an anvil tube 2,
- a clamping tube 5, and

- a set of stapling plungers 6.

On its lower end, the anvil tube 2 carries an anvil 3, the upper side of which is provided with a number of staple-bending recesses 4 adapted to cooperate with and bend an equal number of staples 7, in the situation shown in Figure 1 being temporarily held lightly in an equal number of staple-holding recesses 8 formed in the lower ends of the stapling plungers 6.

Figure 2 shows the situation, in which the instrument is made ready for use by the operating surgeon. As mentioned initially, the anastomosis instrument shown is primarily developed for use when performing coronary bypass operations, and to this end, a bypass vessel 9 - that may be a vein taken from some other part of the patient's body - has been inserted in the anvil tube with its lower end everted about the anvil 3 and with its end region 10 covering the staple-bending recesses 4 in the upper surface of the anvil 3. At this point it should be noted that the bypass vessel 9 may have a considerably larger circumference than the inside of the anvil tube 2, consequently lying more or less folded in the longitudinal direction in the latter, for which reason the action of everting its end region 10 about the anvil 3 does not necessarily entail undue stretching of the bypass vessel 9.

Figure 3 shows the instrument having been made ready as shown in Figure 2 inserted in an opening in a coronary artery 11, said opening having an edge region 12 which, due to the elasticity of the tissue of the coronary artery 11, will embrace the anvil tube 2 in a location close to the anvil 3. The opening in the coronary artery 11 may

e.g. have been formed according to the method described in the international application with publication No. WO 95/17127 with the title "Method and instrument for establishing the receiving side of a coronary artery bypass graft".

As soon as the operating surgeon in the situation shown in Figure 3 has ascertained that the edge region 12 embraces the anvil tube 2 closely on all sides, he or she will proceed to the situation shown in Figure 4, in which the clamping tube 5 has been moved towards the anvil 3 so as to clamp the edge region 12 on the coronary artery 11 and the end region 10 on the bypass vessel 9 firmly together in readiness for the next step shown in Figure 5, in which the stapling plungers 6 have been moved downwardly so as to cause the staples 7 to penetrate the edge region 12 and the end region 10 and engage the staple-bending recesses 4, by which they will be bent in a tangential direction in a similar manner as is known from both surgical staplers and ordinary office staplers.

In the situation shown in Figure 6, the clamping tube 5 together with the stapling plungers 6 have been moved outwardly and away from the staples 7, the staple-holding recesses 8 due to their light holding action having let go of the staples 7, the latter also having been anchored in the end region 10 by their bent ends.

Figure 7 shows the situation, in which the operation of removing the anastomosis instrument 1 from the coronary artery 11 and its anastomosis with the bypass vessel 9 has begun. As will be seen from Figures 6 and 7, the circumferential pocket formed by the eversion of the lower end of the bypass vessel 9 will now open and allow the anvil 3 to be removed by luxation, Figure 8 showing the

situation after such removal, resulting in a finished anastomosis of the intima-to-intima type considered most desirable for this type of operation.

The three main components of the anastomosis instrument 1 referred to above, i.e. the anvil tube 2, the clamping tube 5 and the set of stapling plungers 6, will, of course, have to be connected to some kind of operating members to enable the operating surgeon and his or her assistants to carry out the steps shown in Figures 1-8. Theoretically, these operating members could consist of three tubes (not shown), viz.

- a relatively long holding tube in continuation of the anvil tube 2,
- a somewhat shorter clamping tube in continuation of the clamping tube 5, and
- an even shorter stapling tube, to which the stapling plungers 6 are connected.

As is well-known, however, coronary bypass operations, especially according to the method subject to the international application No. WO 95/17127 entitled "Method and instrument for establishing the receiving site of a coronary artery bypass graft", should be carried out as rapidly as possible, and for this reason, the "theoretical" embodiment shown in Figures 1-7 is too cumbersome to work with to ensure a sufficiently rapid operating procedure. As mentioned above, Figures 9-12 illustrate an embodiment of an anastomosis instrument, that is highly suitable for creating an end-to-side anastomosis in a very short time.

Due to the construction of the instrument shown in Figures 9-12 it is not possible to make an easily understandable

drawing in the nature of the simple drawings of Figures 1-7. For this reason, the "active" parts of the instrument have been shown in perspective, and with the exception of the anvil and its supporting columns, with one half removed along a longitudinal sectional plane, so that the remaining half can be seen partly from the inside, partly from the outside. In Figures 9-12, those of the components functionally corresponding to components shown in Figures 1-7 have been given the same reference numbers with 100 added, whereas components not having "opposite numbers" in Figures 1-7 have been given the reference numbers of the components, with which they are most closely associated, with the addition of a capital letter.

As shown in Figure 9, the anastomosis instrument 101 comprises a number of parts functionally corresponding to parts of the instrument shown in Figures 1-7, viz.:

- an anvil tube 102,
- an anvil 103,
- a clamping tube 105, and
- a set of stapling plungers 106.

Although the basic functions of these parts are the same as the basic functions of the corresponding parts in the embodiment of Figures 1-7, the arrangement differs somewhat from that of the latter, as will be evident from the following.

In contrast to the anvil tube 2 of Figure 1, the anvil tube 102 of Figure 9 extends on the outside of the instrument and is terminated by an end wall 102A, to which the anvil 103 is secured at a distance by means of two columns, viz. an upstream column 103A and a downstream column 103B. The expressions "upstream" and "downstream"

refer to the direction of blood flow in the artery, in which the instrument 101 will normally, but not necessarily exclusively, be used in creating an end-to-side anastomosis.

To make it possible to insert the bypass vessel (not shown) corresponding to the bypass vessel 9 shown in Figures 1-8, all transversely oriented components have suitable openings, of which the forwardmost opening 103C is formed in the anvil 103, the latter being provided with staple-bending recesses 104 having the same function as the staple-bending recesses 4 shown in Figure 1.

As will be seen from Figures 9-12, the various components are not rotationally symmetrical about the longitudinal axis of the instrument, as the anvil 103 has been made "boat-shaped" to make it easier to insert it in the opening in the artery and to make it easier for the edges of the opening to fit in with the upper side of the anvil 103 with the stapling recesses 104.

Due to the arrangement of the anvil tube 102 as the outermost component terminated by the end wall 102A, it is not possible in this embodiment to let the clamping tube 105 extend in its full circumferential width all the way towards the upper face of the anvil 103. For this reason, the clamping tube 105 is terminated by an end wall 105A, from which a set of clamping columns 105B extend in the forward (downward) direction through suitable openings in the anvil tube end wall 102A.

The stapling plungers 106 are guided in the longitudinal direction in suitable guides in the clamping columns 105B, and their rearmost (uppermost) ends are secured to

a stapling plunger carrier 106A, itself secured to and terminating a stapling tube 106B, through which the force for actuating the stapling plungers 106 may be transmitted from a suitable operating device. Figures 9-12 show neither staples corresponding to the staples 7 of Figure 1 nor staple-holding recesses corresponding to the staple-holding recesses 8 shown in Figure 1, but it will be understood that the forwardmost (lowermost) ends of the stapling plungers 106 will be provided with suitable staple-holding recesses capable of holding staples in such a position, that when the stapling plungers 106 are advanced towards the anvil 103, the staples will be bent by the staple-bending recesses 104 in the usual manner.

The relative positions of the various parts as shown in Figure 9 correspond to those shown in Figures 1-3, i.e. there is a sufficient distance between the rearward (upper) face of the anvil 103 and the forward (downward) ends of the clamping columns 105B to accomodate the everted end region of the bypass vessel corresponding to the end region 10 shown in Figure 2, as well as the edge region of the coronary artery concerned corresponding to the edge region 12 of the coronary artery 11 shown in Figure 3.

The situation shown in Figure 10 corresponds to that shown in Figure 4, i.e. the clamping columns 105B have been advanced towards the anvil 103, in Figure 10 leaving a gap symbolizing the presence of the end region of the bypass vessel and the edge region of the coronary artery (all not shown). The movement of the clamping columns 105B has, of course, been effected by advancing the clamping tube 105 to the same extent. To prevent said end and edge regions being crushed in the clamping

operation, suitable stops (not shown) are adapted to stop the movement of the clamping columns 105B towards the anvil 103 so as to leave a gap just sufficient to hold them firmly together. To improve the grip, the clamping surfaces may be provided with elastically flexible fins or fingers. Figure 13 shows how this concept could be applied to the embodiment shown in Figures 1-7, it being - of course - equally applicable to that shown in Figures 9-12, or the apparatus according to the present invention shown in Figures 14-18 and described below.

The relative positions shown in Figure 11 correspond to those shown in Figure 5, i.e. the stapling plungers 106 have now been advanced, guided by the clamping columns 105B so as to bring the staples (not shown) into engagement with the staple-bending recesses 104, thus joining the end region of the bypass vessel to the edge region of the coronary artery (all not shown).

The relative positions shown in Figure 12 correspond to those shown in Figures 6 and 7 and with the exception that in Figure 12, the stapling plungers 106 have not only been withdrawn from the staples joining the two vessels, but have in fact been removed completely from the instrument to make it possible to insert a new set of staples, that may be of the disposable or semi-disposable type.

With the arrangement shown in Figures 9-12, the operating surgeon may literally have a firm grip on the situation by holding the outermost component, i.e. the anvil tube 102, which is rigidly connected to the anvil 103 through the columns 103A and 103B, so that he or she will be able to move the anvil 103 with the everted end of the

bypass vessel into the opening in the coronary artery by direct manual control, and - not least - by "direct mechanical feedback", as the rigid mechanical interconnection between the anvil 103 og the anvil tube 102 enables the surgeon to "feel" whatever object is encountered by the anvil. Advantageously, the rearward (upper) part (not shown) of the instrument may comprise suitable operating devices and/or mechanisms for moving the clamping tube 105 and the stapling plungers 106 relatively to the anvil tube 102 and hence relatively to the anvil 103. Due to the extremely limited time available for performing coronary bypass operations, these operating devices and/or mechanisms should be designed to enable the operating surgeon to initiate the requisite movements rapidly and with a minimum of effort.

Thus, the operating devices and/or mechanisms could be arranged to function under the control of a single operating member, such as a push-button on the rear (upper) end of the instrument adapted to be operated by the surgeon's thumb, in the following manner:

- firstly, when the operating member is moved in a first direction, e.g. a push-button is depressed, the clamping columns 105B will be advanced to their forwardmost (lower) position, in which they clamp the end region of the bypass vessel and the edge region of the opening in the artery together until said stop is reached, and then the stapling plungers 106 will immediately be actuated to staple the two regions together, after which both the clamping columns 105B and the stapling plungers 106 are withdrawn, e.g. by releasing said push-button, and
- secondly, immediately upon the operating member moving in the opposite direction, e.g. when the push-button

has been released, the mechanism is re-set in readiness for a movement in the first direction, after which the instrument can be removed as described above with reference to Figure 7.

The anastomotic instrument according to the present invention shown in Figures 14-18 possesses several features in commom with that of the previous application referred to initially and shown in Figures 11-13, especially Figures 9-12, this being the main reason for including a description of the previous embodiments in order to make it easier to understand the functioning of the instrument according to the present invention.

Looking at Figure 14, showing some of the essential parts of the instrument, it will be seen that the instrument comprises a number of components with the same functions as those of the instrument shown in Figures 9-12. At this stage it should be noted that the instrument is adapted to be split along a longitudinal dividing plane, and Figure 14 shows solely the parts on one side of this plane.

The reference numerals of the parts shown in Figures 14-18 are mostly the same as those of parts having similar functions down in Figures 9-12 with 100 or 200 added.

Thus, the parts shown in Figures 14-18 of the anastomotic instrument 201 of the present invention comprise a first rigid assembly or anvil assembly having

- an anvil carrier upstream half 202A, in operation being releasably connected to a similar anvil carrier downstream half 302A shown in Figure 15 by means of two connecting knobs 202D engaging in suitable recesses

(not visible) in said downstream half 302A,

- a lower jaw 202C of the instrument 201, the latter being shaped like a pair of tongs (vide Figure 15), and
- an anvil upstream half 203 rigidly connected to the anvil carrier upstream half 202A through an anvil upstream column 203A and having two staple-bending recesses 204 as well as two connecting knobs 203D for releasable connection to an anvil downstream half 303 shown in Figure 15.

This first rigid assembly generally corresponds to the assembly shown in Figures 9-12 comprising

- the anvil tube 102 with its end wall 102A and
- the anvil 103 with staple-bending recesses 104 and connected to said end wall 102A through two anvil columns 103A and 103B.

A second rigid assembly or clamping assembly, movable relative to said first rigid assembly, comprises

- a clamping column carrier consisting of an upstream half 205A and a downstream half 305A, releasably interconnected by means of connecting knobs 205D on said upstream half cooperating with recesses (not visible) in the downstream half, rigidly connected to the uppermost end of
- four upstream and downstream clamping columns 205B and 305B respectively, slidable in and extending through the respective anvil carrier halves 202A and 302A so as to be capable of being moved into abutment with the upper side of the anvil upstream and downstream halves 203 and 303 respectively in the same manner as shown in Figures 4 and 10 depicting the earlier instrument.

This second rigid assembly will be seen generally to

correspond to the assembly shown in Figures 9-12 comprising

- the clamping tube end wall 105A and
- the clamping columns 105B.

A third rigid assembly or stapling assembly, movable relative to said first (anvil) and second (clamping) rigid assemblies, comprises

- a stapling plunger carrier consisting of an upstream half 206A and a downstream half 306A, releasably interconnected by means of connecting knobs 206D on said upstream half cooperating with recesses (not visible) in the downstream half, rigidly connected to the uppermost ends of
- four upstream and downstream stapling plungers 206 and 306 respectively, slidable in guideways in the upstream and downstream clamping columns 205B and 305B respectively, thus extending through both the clamping carrier halves 205A and 305A and the anvil carrier halves 202A and 302A respectively, so as to make it possible to advance the stapling plungers 206 and 306 carrying staples (not shown) in their lowermost ends into cooperation with the staple-bending recesses 204 and 304 in the upper sides of the anvil halves 203 and 303 respectively in the same manner as shown in Figures 5 and 11 depicting the earlier instrument.

This third rigid assembly will be seen generally to correspond to the assembly shown in Figures 9-12 comprising

- the stapling plunger carrier 106A, and
- the stapling plungers 106.

After having read the explanation of the functioning of

the examples shown in Figures 1-8 and 9-12 respectively, the reader should turn the attention to Figure 15.

As will be evident from said explanation, the relative movements between the anvil assembly, the clamping assembly and the stapling assembly should take place in a certain sequence, i.e.

I moving the clamping assembly relative to the anvil assembly so as to make the clamping columns 205B and 305B clamp the tissue regions 10 and 12 (cf. Figure 4) together,

II moving the stapling assembly relative to the anvil assembly so as to staple the tissue regions 10 and 12 to each other (cf. Figure 5), and

III moving the clamping assembly and the stapling assembly together in the opposite directions relative to the anvil assembly so as to make it possible to liberate the instrument from the anastomosis having been established (cf. Figures 6-8).

An important feature of the present invention is the use of elastic means having different spring characteristics to effect these relative movements. The reader is asked to imagine two compression springs or sets of same, the first of which is placed between the clamping column carrier 205A, 305A and the anvil column carrier 202A, 302A and is relatively soft, i.e. needs relatively little force to be compressed, the second being placed between the stapling plunger carrier 206A, 306A and the clamping column carrier 205A, 305A and is relatively stiff.

Now, slowly squeezing the three assemblies between the lower jaw 202C and the upper jaw 206C will first compress

the relatively soft first spring between the clamping column carrier 205A, 305A and the anvil column carrier 202A, 302A, thus effecting the relative movement I above, i.e. the clamping movement (cf. Figure 4).

When the clamping columns 205B and 305B have arrived at their clamping position, they cannot be moved further, and continued squeezing will cause compression of the second spring or set of springs between the stapling plunger carrier 206A, 306A and both the clamping and anvil assemblies, so that the stapling plungers will be moved according to the relative movement II above (cf. Figure 5), thus completing the stapling operation and creating the anastomosis.

Finally, relaxing the grip will allow the springs to return the parts to the initial relative positions shown in Figure 15 (cf. also Figures 6-8), so that the instrument may be removed in a manner corresponding to that shown in Figures 7 and 8.

The purpose of dividing the three assemblies in upstream and downstream halves is to make it possible

- firstly, with the upstream and downstream halves unified as shown in Figure 15, to fit the instrument with a graft vessel (not shown) in a manner like that shown in Figure 2,
- secondly, to establish the anastomosis in a manner like that shown in Figures 3-8, and
- thirdly, according to the present invention, to split the three assemblies lengthwise, so as to make it possible to remove the instrument from a graft vessel that - typically because it has already been anastomotized or has an anatomically fixed origin at

the opposite end - cannot be pulled out of the assemblies (cf. Figures 7 and 8).

For the above purpose, the present invention specifies the use of the elastic member 410 shown in Figures 16-18, best understood by also looking at Figures 14 and 15. This elastic member 410 serves three functions, viz.:

a) keeping the upstream and downstream halves of the three rigid assemblies together during the steps of fitting the instrument with a graft vessel and establishing the anastomosis,

b) providing the different spring characteristics necessary for the various relative movements to take place in the correct sequence as explained above, and

c) making it possible, in a manner to be explained, to separate the upstream and downstream parts from each other to enable them to be removed sideways from the graft vessel.

Thus, the embodiment of the elastic member 410 shown in Figures 16-18 constitutes a sheath of rubber or rubber-like material (in the following referred to as "rubber") embracing closely and in elastic tension

- the two anvil carrier halves 202A and 302A,
- the two clamping column carrier halves 205A and 305A, and
- the two stapling plunger carrier halves 206A and 306A, for this purpose having internal gripping grooves 411, 412 and 413 respectively cooperating with gripping flanges 202G, 302G, 205G, 305G, 206G and 306G respectively.

Thus, when properly assembled, the three relatively movable assemblies, i.e. the anvil assembly, the clamping

assembly and the stapling assembly described above, together with the rubber sheath 410, present themselves as a unified solid body with the external appearance shown in Figure 17. Thus, the rubber sheath 410 can serve function a mentioned above.

As will be evident from Figures 15 and 18, the rubber sheath 410 comprises two axially springy segments with different spring characteristics, viz.:

- a relatively soft segment 414 between the gripping grooves 411 and 412 for the anvil carrier 202A, 302A and the clamping column carrier 205A, 305A respectively, and
- a relatively stiff segment 415 between said gripping groove 412 and the gripping groove 413 for the stapling plunger carrier 206A, 306A.

Thus, the rubber sheath 410 can also serve function b referred to above in the manner explained further above using imaginary springs as an example.

When the anastomosis has been established and the instrument is to be removed, the rubber sheath 410 is cut open lengthwise by means of a suitable cutting instrument capable of making a cut all the way through the sheath 410. Such a cutting instrument could be or comprise a knife with indents in the cutting edge for the three gripping flanges 202G, 205G and 206G and/or 302G, 305G and 306G. According to the present invention, however, it is preferred to use one or two cutting wires (not shown) placed on the internal surface of the sheath 410 and having pulling loops or the like (likewise not shown), making it possible to cut the sheath 410 open in a manner known from various types of sealed packages.

Thus, function c referred to above can also be achieved by using the rubber sheath 410 according to the present invention.

List of Parts

1	anastomosis instrument
2	anvil tube
3	anvil
4	staple-bending recess
5	clamping tube
6	stapling plunger
7	staple
8	staple-holding recess
9	bypass vessel
10	end region
11	coronary artery
12	edge region
13	fin or finger
101	anastomosis instrument
102	anvil tube
102A	(anvil tube) end wall
103	anvil
103A	(anvil) upstream column
103B	(anvil) downstream column
103C	(anvil) opening
104	staple-bending recess
105	clamping tube
105A	(clamping tube) end wall
105B	clamping column (and stapling-plunger guide)
106	stapling plunger
106A	stapling plunger carrier
106B	stapling tube

201	anastomotic instrument
202A	anvil carrier upstream half
202C	lower jaw
202D	connecting knob
202G	gripping flange
203	anvil upstream half
203A	anvil upstream column
203D	connecting knob
204	staple-bending recess
205A	clamping column carrier upstream half
205B	upstream clamping column (and stapling plunger guide)
205D	connecting knob
205G	gripping flange
206	stapling plunger
206A	stapling plunger carrier upstream half
206C	upper jaw
206G	gripping flange
302	anvil carrier downstream half
302G	gripping flange
303	anvil downstream half
303A	anvil downstream column
305A	clamping column carrier downstream half
305B	downstream clamping column (and stapling plunger guide)
305G	gripping flange
306	stapling plunger
306A	stapling plunger carrier downstream half
306G	gripping flange

410 elastic member/rubber sheath
411 internal gripping groove
412 internal gripping groove
413 internal gripping groove
414 relatively soft segment
415 relatively stiff segment

CLAIMS

1. Method of connecting an end region (10) of a first vessel (9) to the side of a second vessel (11) by carrying out an end-to-side anastomosis, said method being of the kind comprising the following steps a-d:

a) forming an opening in the side of said second vessel (11),

b) inserting in said opening an anastomosis instrument (201) carrying said first vessel (9) in a central longitudinal cavity and with said end region (10) everted about a circumferential member (203, 303) constituting a forward portion of said instrument (201) in such a manner, that the intima side of said end region (10) comes into contact with the intima side of said second vessel (11) at an edge region (12) of said opening,

c) joining said end region (10) to said edge region (12) by inserting penetratingly therethrough and leaving therein a plurality of spiked members, and

d) removing said instrument (201) from the joint formed between said first (9) and second (11) vessels,

said steps a-d being carried out by

e) the use of an anastomosis instrument (201) comprising

e1) an anvil assembly (202A, 302A, 203, 303, 203A, 303A) comprising a circumferential anvil member (203, 303) and in which said first vessel (9) may be placed with its end region (10) everted about said anvil member (203, 303) with the terminal part of said end region facing rearwardly,

e2) rearwardly facing staple-bending recesses (204, 304) provided in said anvil member (203, 303),

e3) a clamping assembly (205A, 305A, 205B, 305B) movable relative to said anvil assembly and comprising

clamping members (205B, 305B) adapted to be moved towards said anvil member (203, 303) so as to make it possible to clamp together therebetween said end region (10) on said first vessel (9) and an edge region (12) on said second vessel (11), and

e4) a stapling assembly (206, 306, 206A, 306A) comprising stapling plungers (206, 306) movable relative to said anvil assembly and said clamping assembly and adapted to insert staples (7) penetratingly through said clamped end (10) and edge (12) regions into engagement with said stapling-bending recesses (204, 304) so as to bend permanently said staples (7) into a shape, in which they hold said end (10) and edge (12) regions together,

characterized by

f) the use of an instrument (201), in which said anvil, clamping and stapling assemblies are capable of being divided and the divided parts separated along said central longitudinal cavity extending generally in the direction of relative movement of said three assemblies and dividing said assemblies in a manner allowing the separated parts to be removed from said first vessel (9) in a transverse direction.

2. Method according to claim 1, characterized by the use of a common sheath-like circumferentially elastic member (410) of rubber or rubber-like material placed in circumferentially elastic tension about said separable parts of said anvil, clamping and stapling assemblies.

3. Method according to claim 1 or 2, characterized by the use of an instrument (201) comprising

a) a first, relatively soft compressionally elastic member (414) between said anvil and said clamping

assemblies,

b) a second, relatively stiff compressionally elastic member (415) between said clamping and said stapling assemblies, and

c) a manually operable implement (202C, 206C etc.) adapted to press said stapling and said anvil members towards each other.

4. Method according to claims 2 and 3, characterized by the use of an instrument (201, in which said first (414) and second (415) compressionally elastic members constitute integral parts of the sheath-like circumferentially elastic member (410) of rubber or rubber-like material.

5. Anastomotic instrument (201) for carrying out the method of claim 1 and comprising

a) an anvil assembly (202A, 302A, 203, 303, 203A, 303A) comprising a circumferential anvil member (203, 303) and in which said first vessel (9) may be placed with its end region (10) everted about said anvil member (203, 303) with the terminal part of said end region facing rearwardly,

b) rearwardly facing staple-bending recesses (204, 304) provided in said anvil member (203, 303),

c) a clamping assembly (205A, 305A, 205B, 305B) comprising stapling plungers (206, 306) movable relative to said anvil assembly and comprising clamping members (205B, 305B) adapted to be moved towards said anvil member (203, 303) so as to make it possible to clamp together therebetween said end region (10) on said first vessel (9) and an edge region (12) on said second vessel (11), and

d) a stapling assembly (206, 306, 206A, 306A) movable

relative to said anvil assembly and said clamping assembly and adapted to insert staples (7) penetratingly through said clamped end (10) and edge (12) regions into engagement with said stapling-bending recesses (204, 304) so as to bend permanently said staples (7) into a shape, in which they hold said end (10) and edge (12) regions together,

characterized by

e) the use of an instrument (201), in which said anvil, clamping and stapling assemblies are capable of being divided and the divided parts separated along said central longitudinal cavity extending generally in the direction of relative movement of said three assemblies and dividing said assemblies in a manner allowing the separated parts to be removed from said first vessel (9) in a transverse direction.

6. Anastomotic instrument according to claim 5, characterized by a common sheath-like circumferentially elastic member (410) of rubber or rubber-like material placed in circumferentially elastic tension about said separable parts of said anvil, clamping and stapling assemblies.

7. Anastomotic instrument according to claim 5 or 6, characterized by

a) a first, relatively soft compressionally elastic member (414) between said anvil and said clamping assemblies,

b) a second, relatively stiff compressionally elastic member (415) between said clamping and said stapling assemblies, and

c) a manually operable implement (202C, 206C etc.) adapted to press said stapling and said anvil members

towards each other.

8. Anastomotic instrument according to claim 6 and 7, characterized in that said first (414) and second (415) compressionally elastic members constitute integral parts of the sheath-like circumferentially elastic member (410) of rubber or rubber-like material.

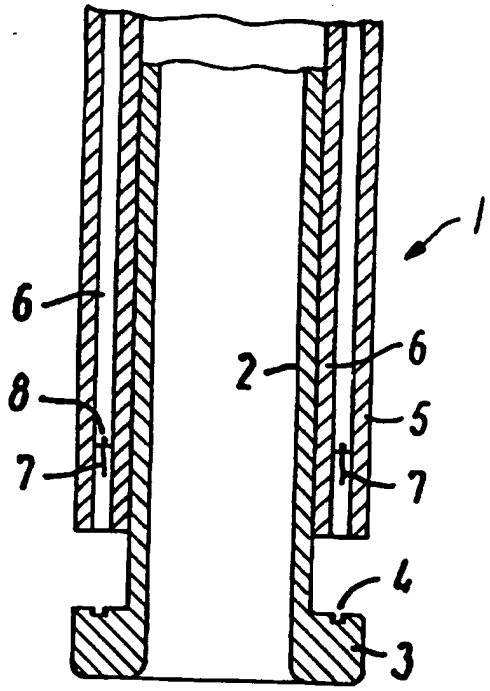

FIG.1

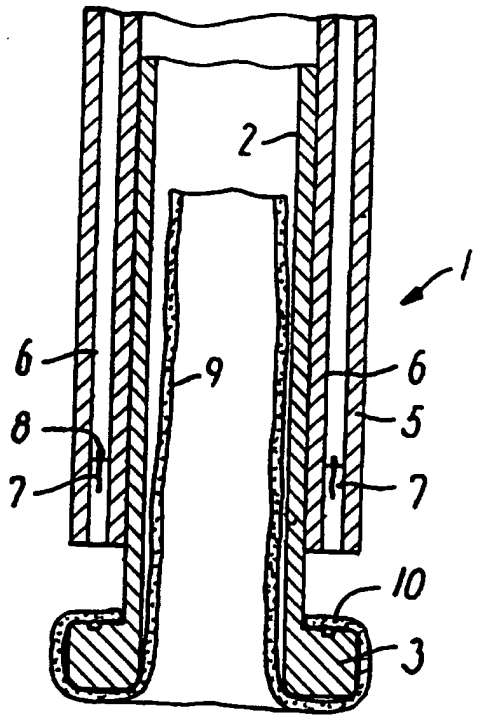

FIG.2

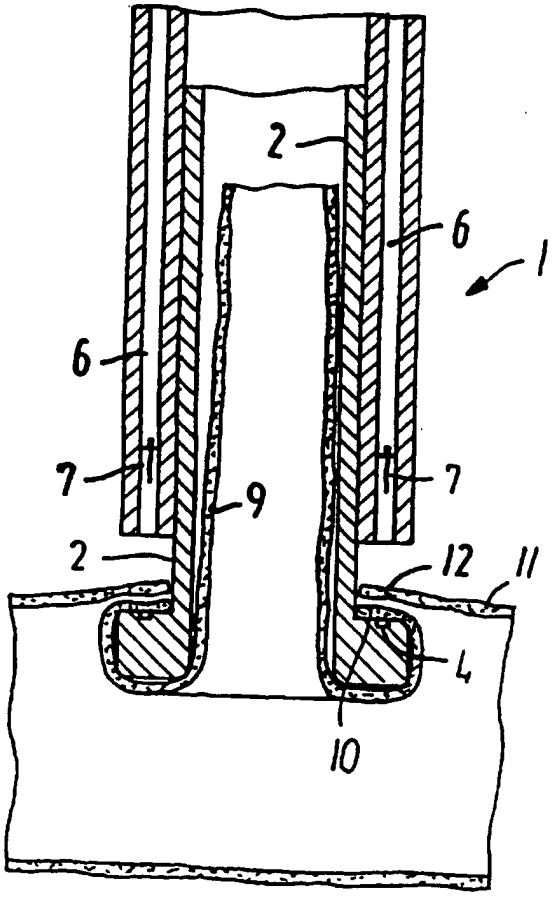

FIG. 3

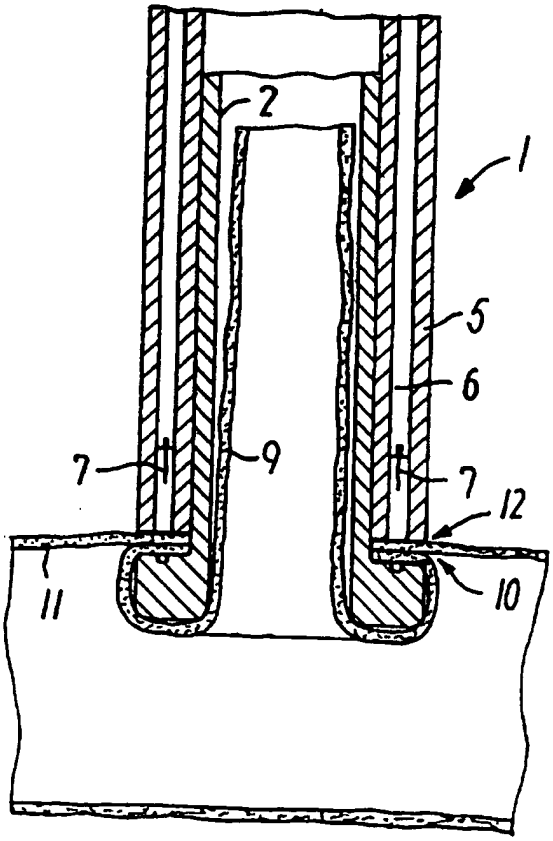

FIG. 4

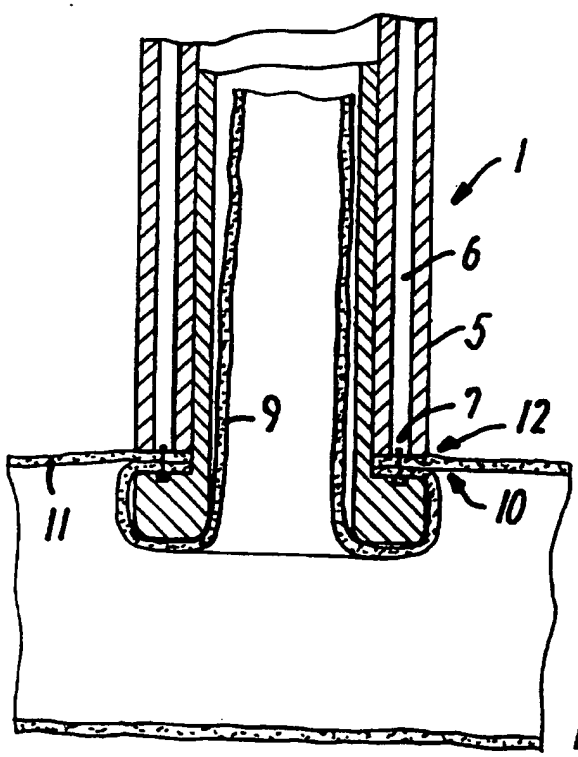

FIG.5

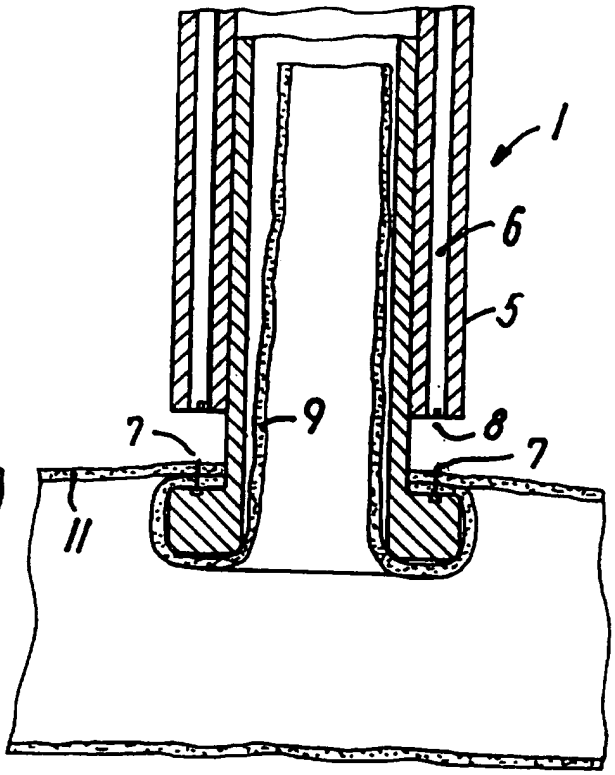

FIG.6

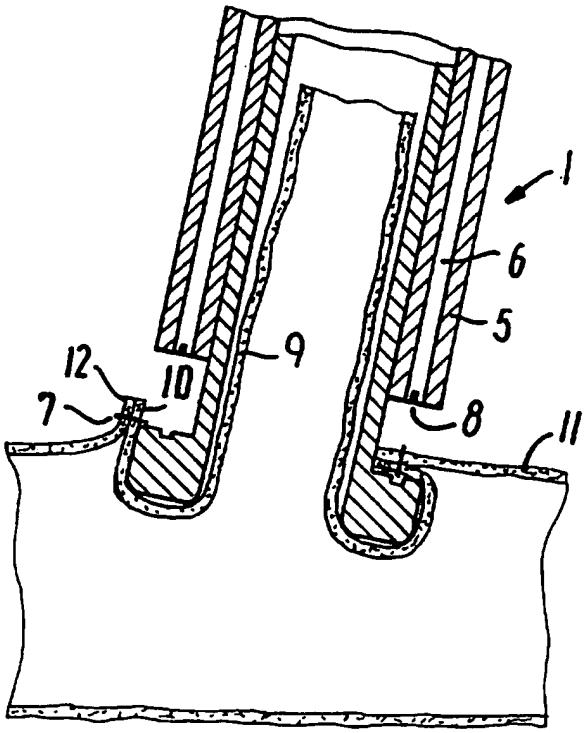

FIG.7

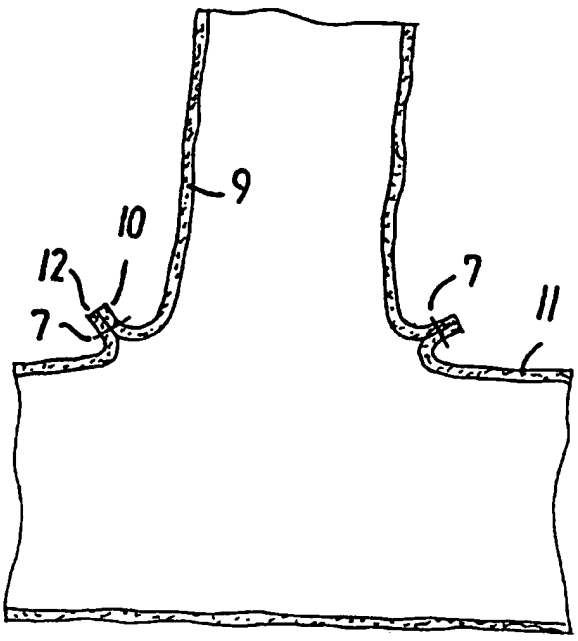

FIG.8

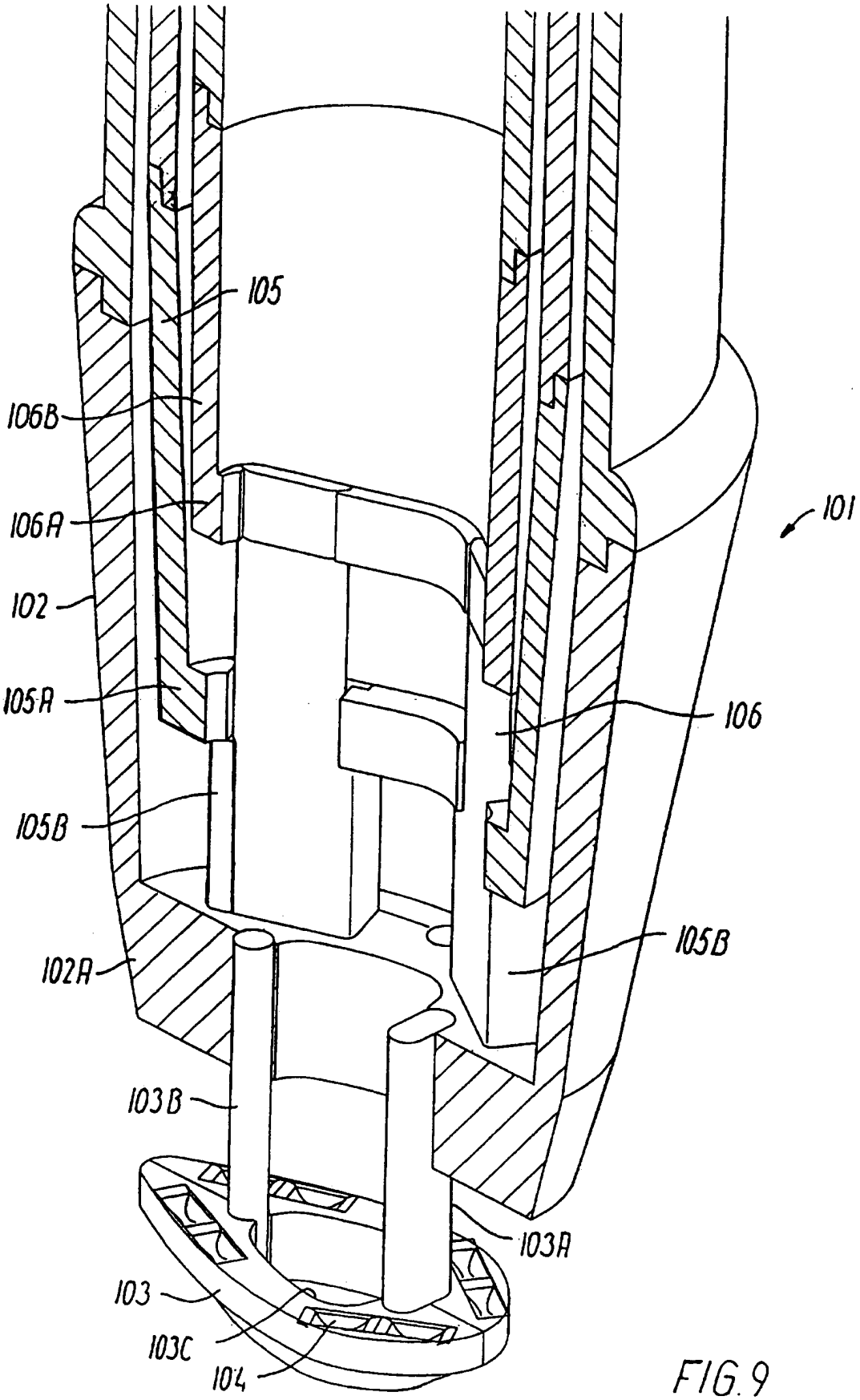
105
106B
106A
102
105A
105B
102A
103B
103
103C
104
101
106
105B
103A

FIG. 9

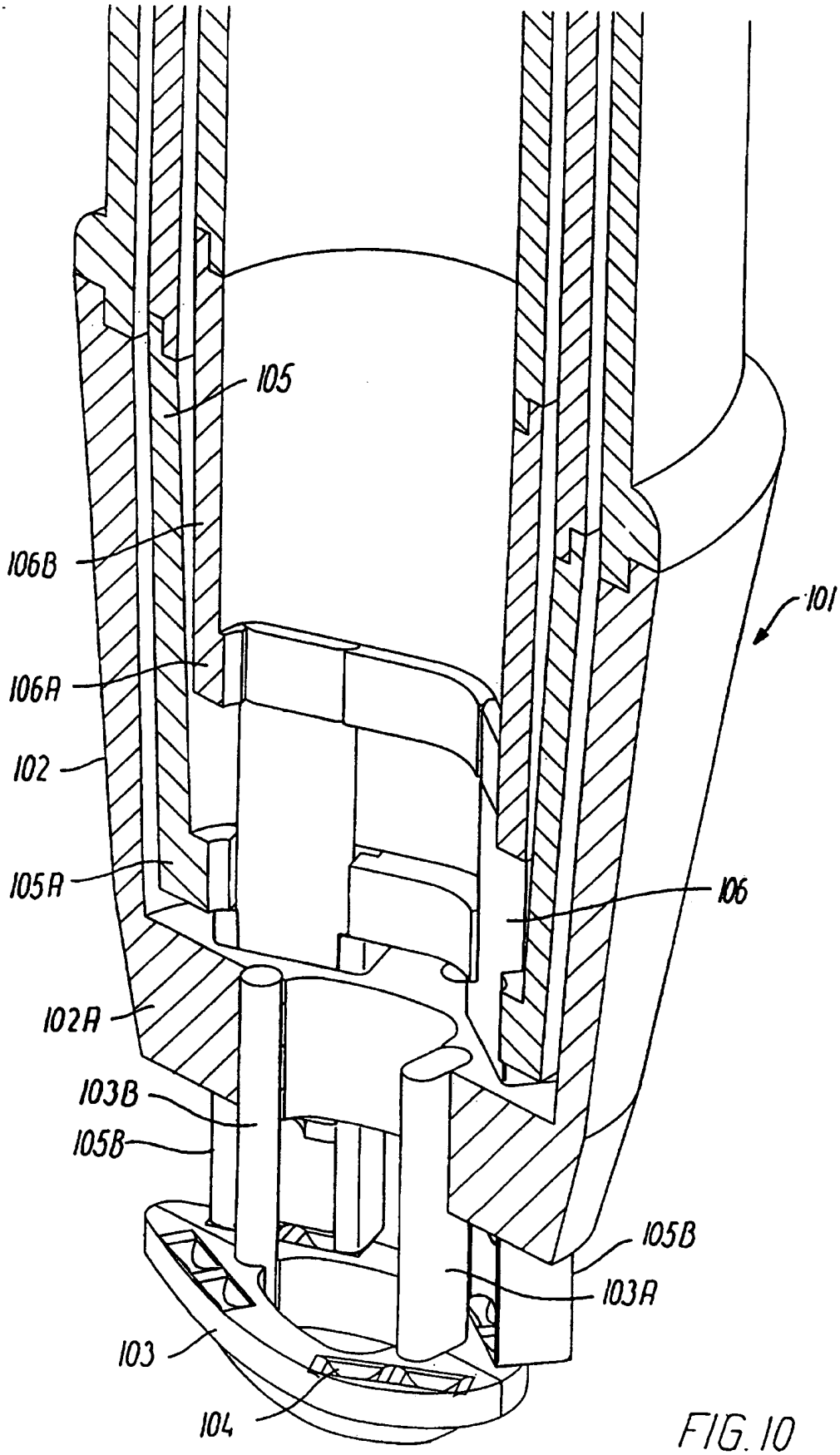
105
106B
101
106A
102
105A
106
102A
103B
105B
105B
103A
103
104

FIG. 10

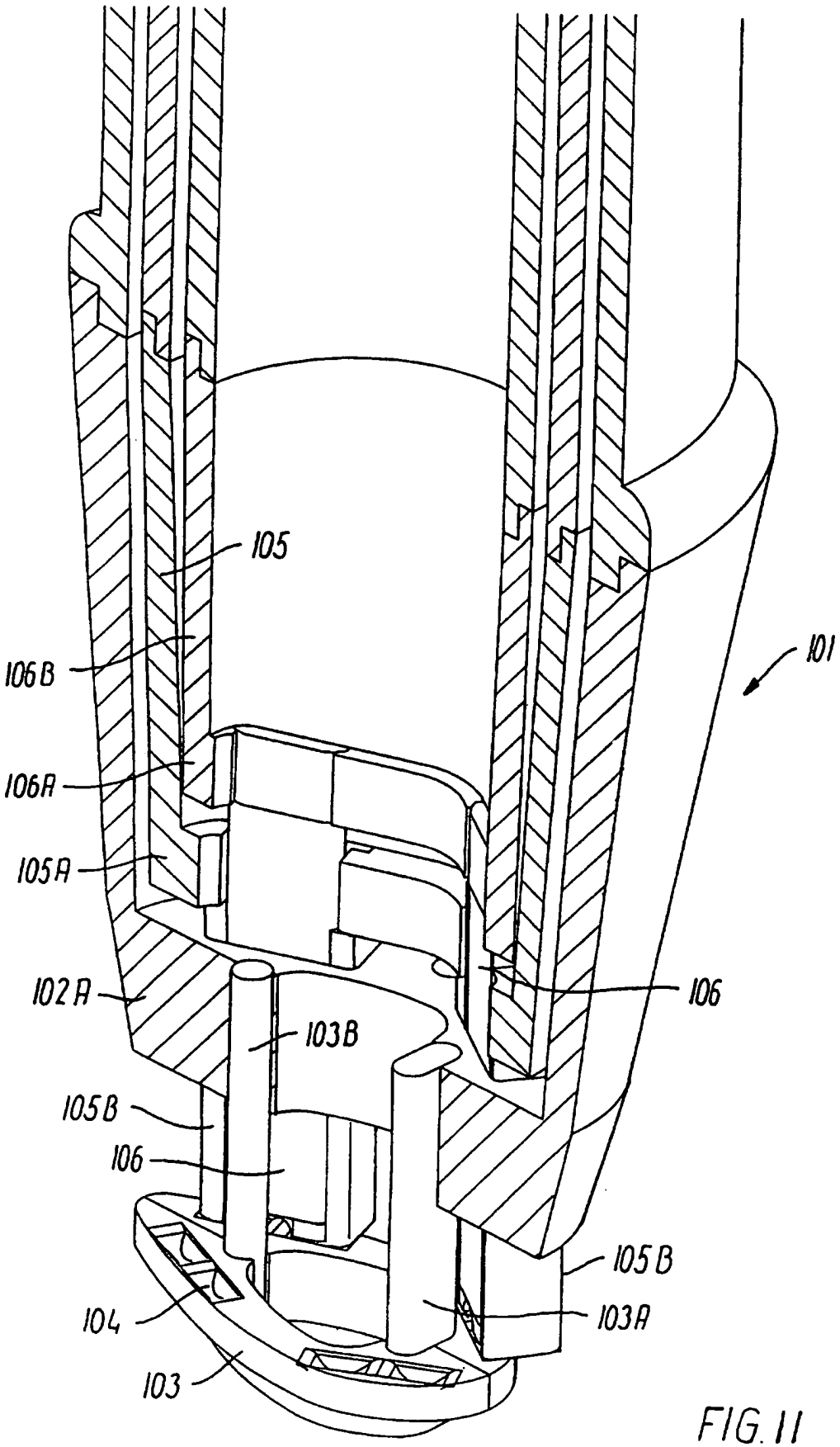
105
106B
101
106A
105A
102A
106
103B
105B
106
105B
104
103A
103

FIG. 11

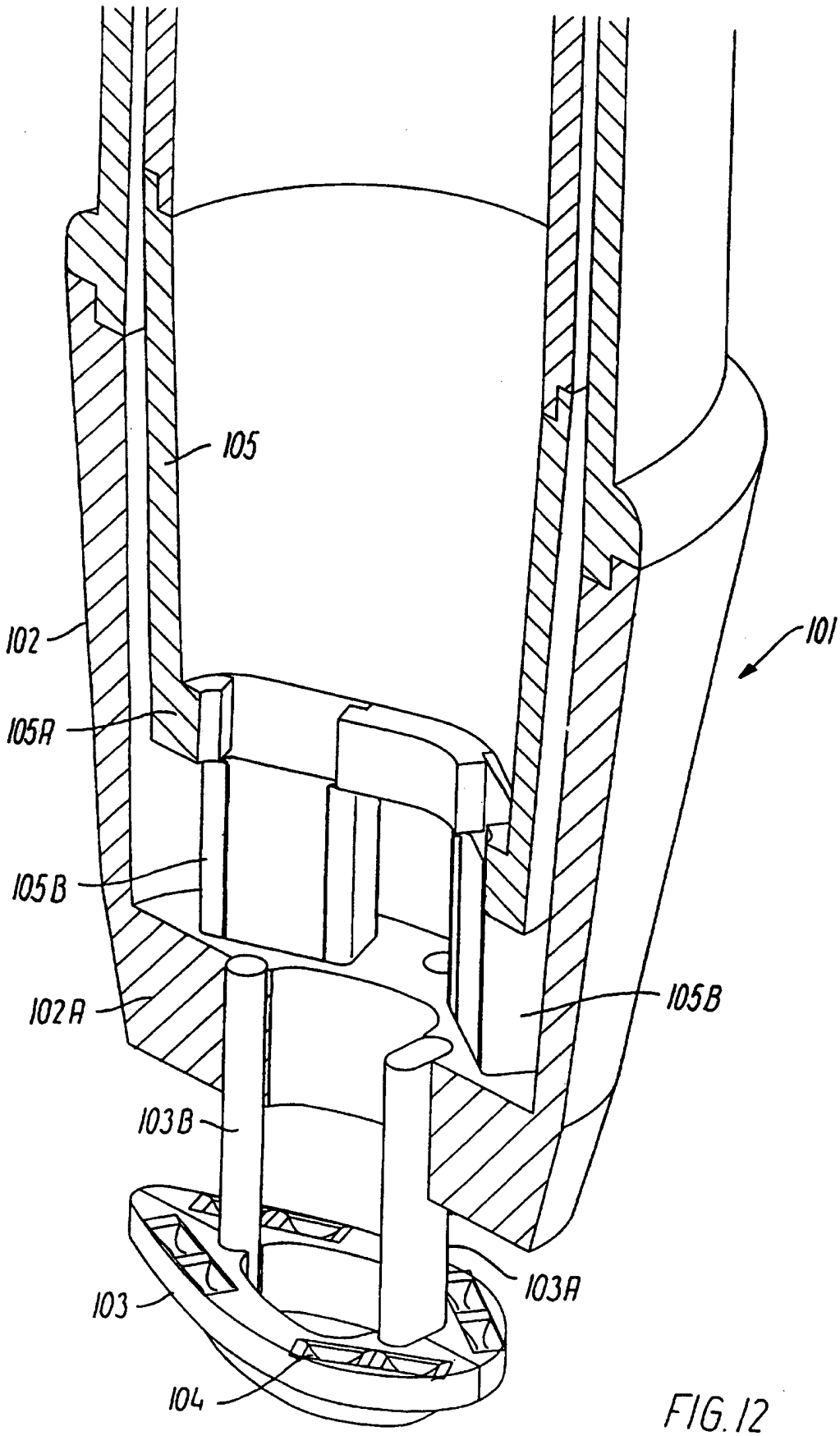

FIG. 12

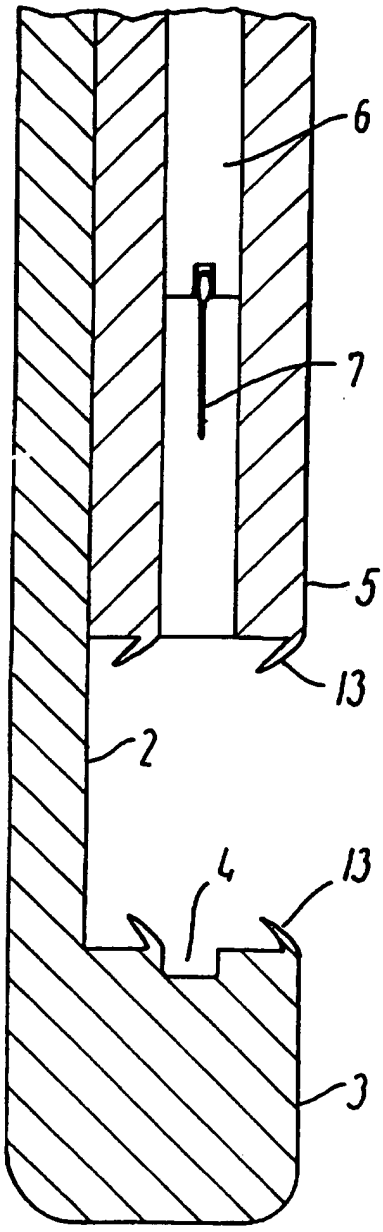

FIG. 13

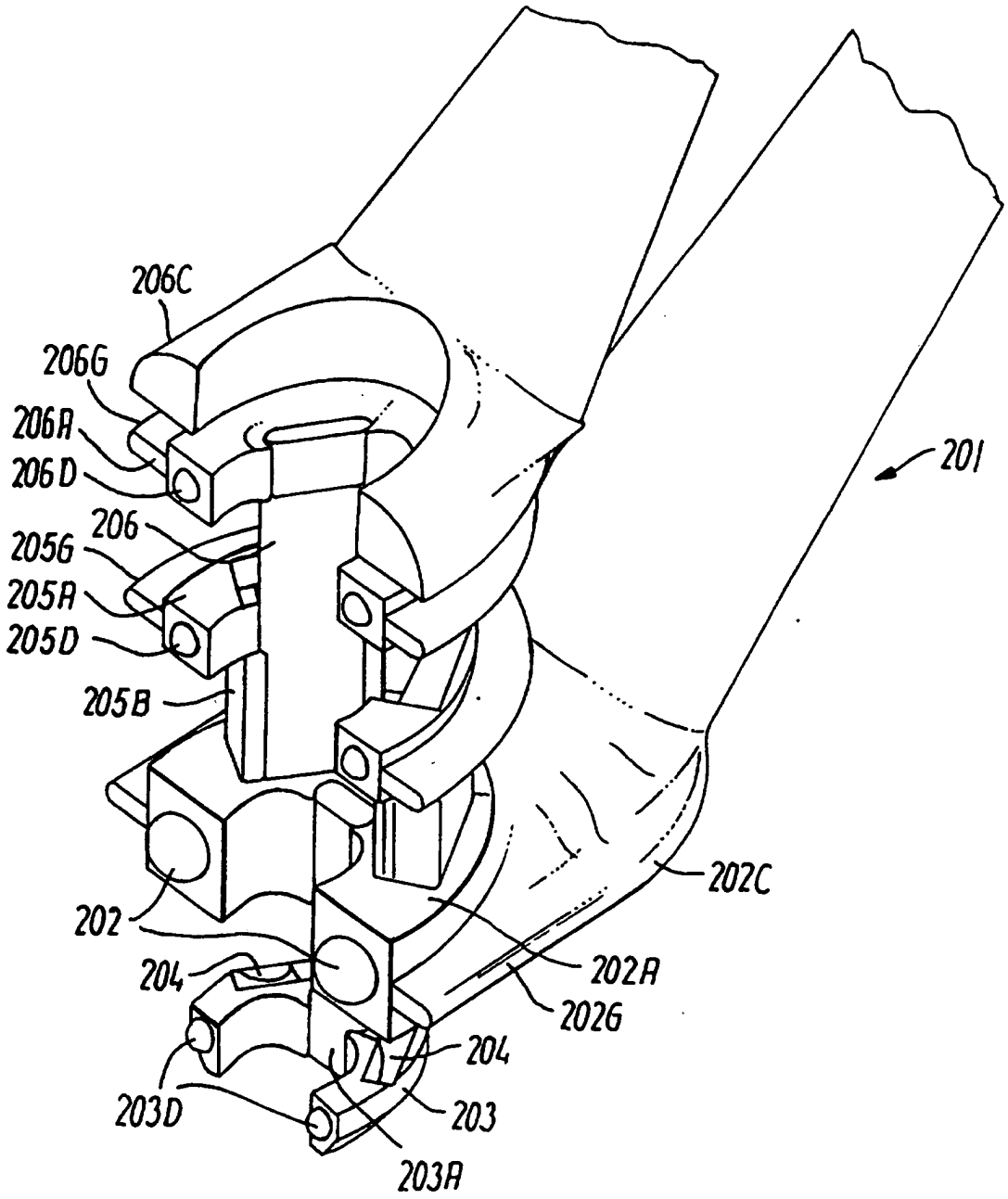
206C
206G
206A
206D
206
205G
205A
205D
205B
201
202C
202
204
202A
202G
204
203D
203
203A

FIG. 14

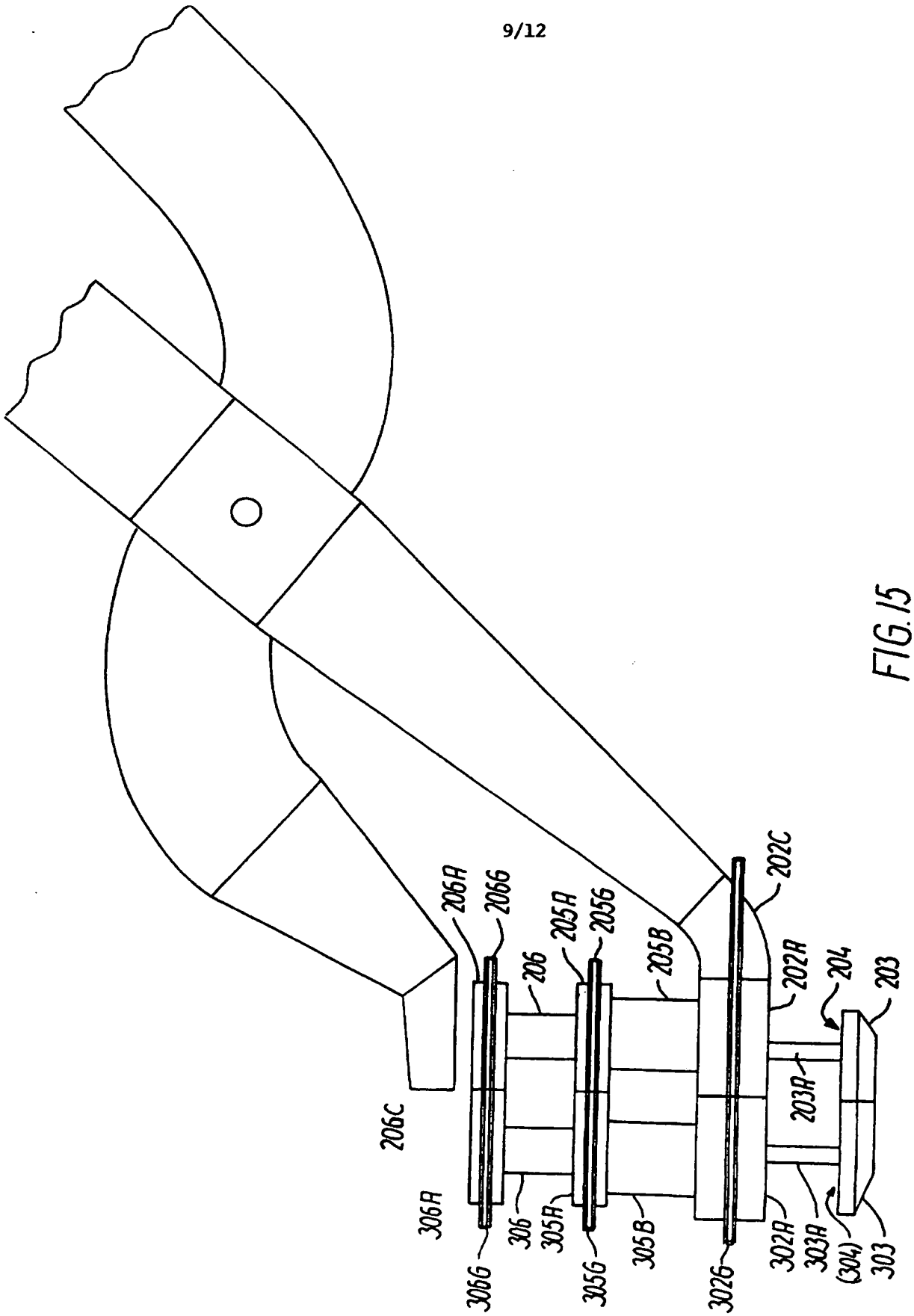
206A
206G
206
205A
205G
205B
202C
202A
204
203
206C
203A
306A
306
305A
305B
302A
303A
(304)
303
306G
305G
302G

FIG. 15

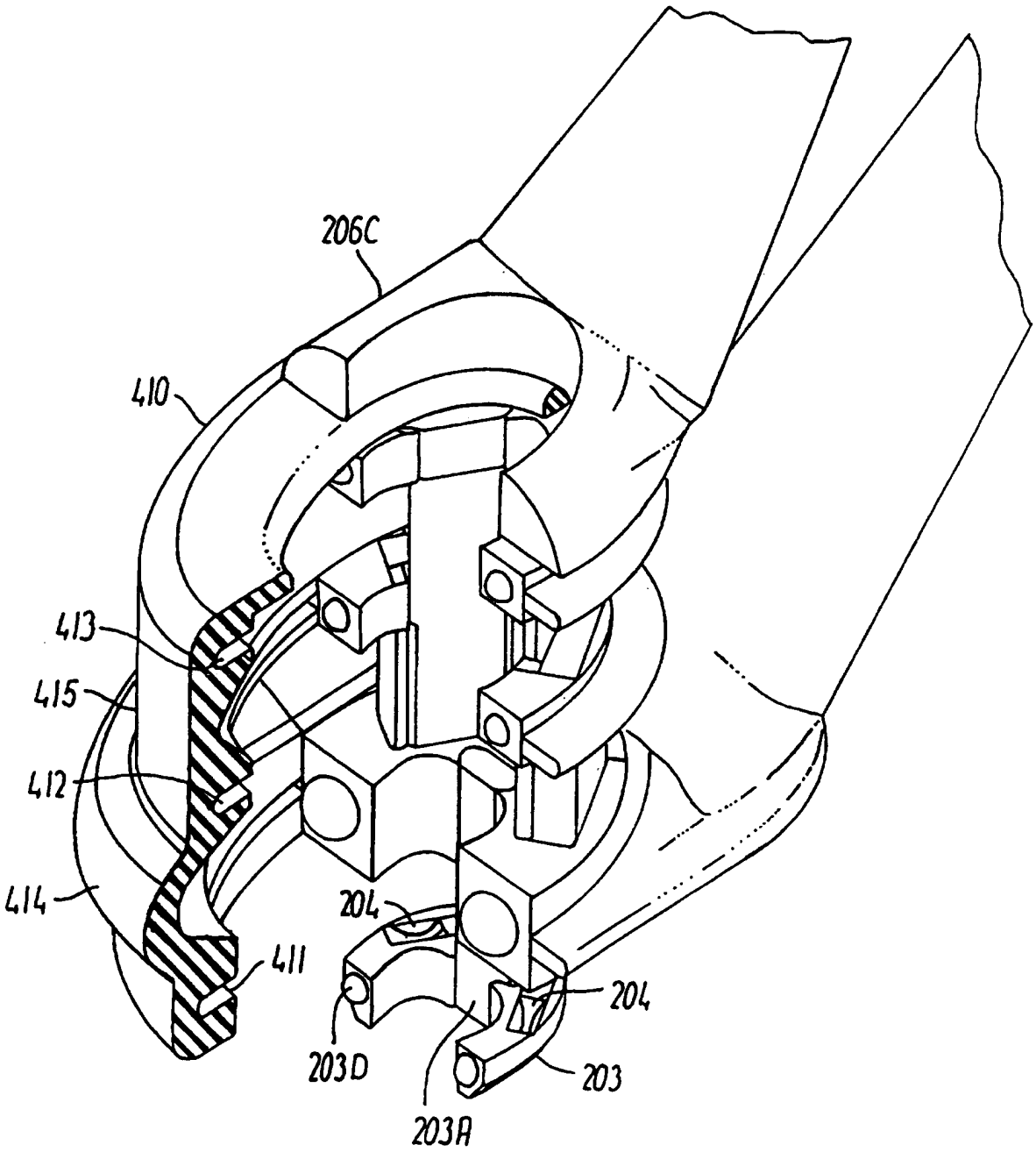

FIG. 16

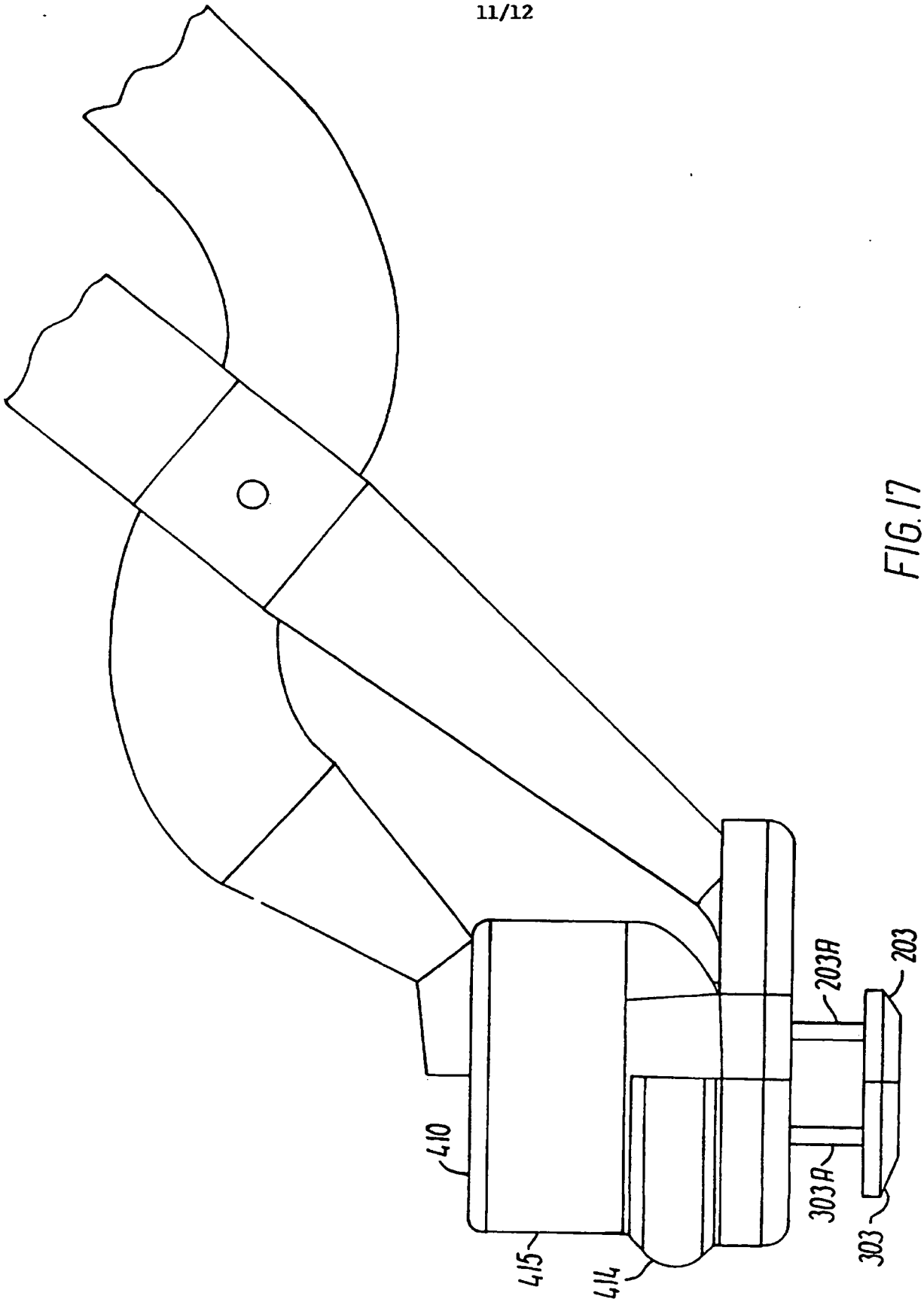

FIG. 17

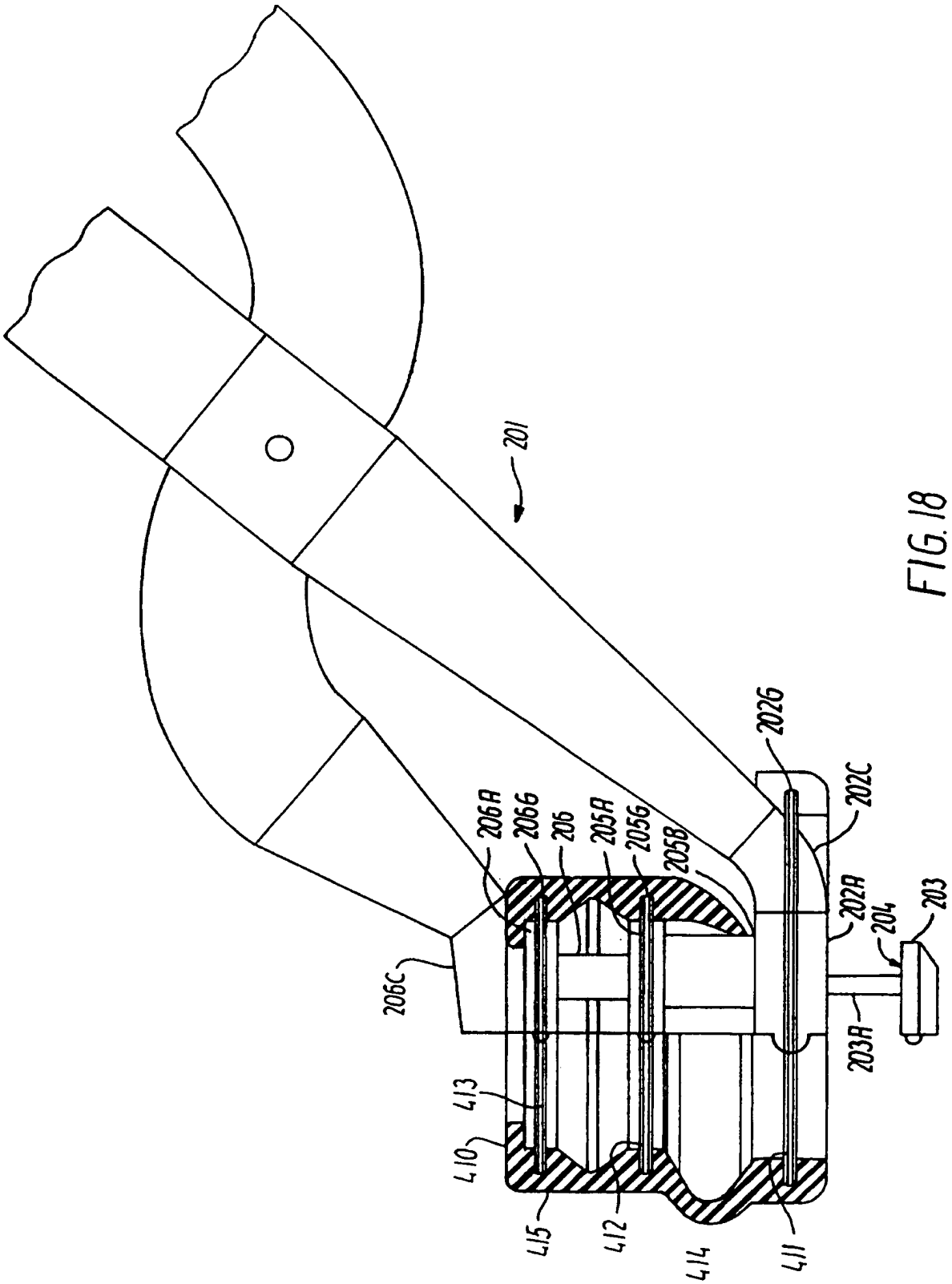
201
206A
206G
206
205A
205G
205B
202G
202C
202A
204
203
206C
203A
413
410
415
412
414
411

FIG. 18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 96/00087

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 17/115
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3519187 A (N.N. KAPITANOV ET AL.), 7 July 1970 (07.07.70), column 2, line 54 - line 63 --	1
A	US 4076162 A (N.N. KAPITANOV ET AL.), 28 February 1978 (28.02.78), column 5, line 39 - line 47 --	1
A	US 5205459 A (R.J. BRINKERHOFF ET AL.), 27 April 1993 (27.04.93), see the whole document --	1
A	US 5292053 A (F. BILOTTI ET AL.), 8 March 1994 (08.03.94), see the whole document --	1

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 October 1996	24 -10- 1996
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Anette Hall Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 96/00087

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5366462 A (R.L. KASTER ET AL.), 22 November 1994 (22.11.94), see the whole document	1

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK96/00087

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1 - 4
because they relate to subject matter not required to be searched by this Authority, namely:

See next sheet.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK96/00087

A method of treatment of the human body by surgery.
This is subject matter which the International Searching Authority is not required to search under Article 17(2)(a)(i) and Rule 39(iv).

A claim is not allowable if it includes at least one feature defining a physical activity or action which constitutes a "method for treatment of the human body by surgery" (Rule 39(iv)).

The characterizing portion of claim 5 is directed to the use of an anastomotic instrument.
Thus, the instrument acquires the nature of a method of treatment by surgery.

Although claim 5, and consequently its dependent claims, is directed to a method of treatment of the human body by surgery, the search has been carried out and based on the anastomotic instrument for carrying out the method.

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/10/96

International application No.
PCT/DK 96/00087

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 3519187	07/07/70	NONE	
US-A- 4076162	28/02/78	CA-A- 1070204	22/01/80
		CH-A- 609550	15/03/79
		DE-A,B,C 2631269	13/01/77
		FR-A,B- 2316910	04/02/77
		GB-A- 1508546	26/04/78
US-A- 5205459	27/04/93	AU-B- 654371	03/11/94
		AU-A- 2109792	25/02/93
		CA-A- 2076602	24/02/93
		EG-A- 19853	31/05/96
		EP-A- 0536882	14/04/93
		GR-A- 92100358	07/06/93
		JP-A- 5212041	24/08/93
		US-A- 5271544	21/12/93
		US-A- 5275322	04/01/94
		US-A- 5285945	15/02/94
		US-A- 5292053	08/03/94
		US-A- 5333773	02/08/94
		US-A- 5350104	27/09/94
		US-A- 5533661	09/07/96
US-A- 5292053	08/03/94	AU-B- 654371	03/11/94
		AU-A- 2109792	25/02/93
		CA-A- 2076602	24/02/93
		EG-A- 19853	31/05/96
		EP-A- 0536882	14/04/93
		GR-A- 92100358	07/06/93
		JP-A- 5212041	24/08/93
		US-A- 5205459	27/04/93
		US-A- 5271544	21/12/93
		US-A- 5275322	04/01/94
		US-A- 5285945	15/02/94
		US-A- 5333773	02/08/94
		US-A- 5350104	27/09/94
		US-A- 5533661	09/07/96
US-A- 5366462	22/11/94	AU-A- 4803593	28/02/95
		WO-A- 9504503	16/02/95
		US-A- 5234447	10/08/93
		US-A- 5403333	04/04/95
		EP-A- 0713373	29/05/96